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November 15, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-4048

Dear Sir/Madam:

The Advanced Medical Technology Association (AdvaMed) provides these comments in response to a request regarding the Food and Drug Administration (FDA or "Agency") Center for Devices and Radiological Health draft guidance *Safer Technologies Program for Medical Devices* (or "STeP"). Notice of this draft guidance and request for comments were published in Federal Register Vol. 84, September 19, 2019.

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed appreciates the opportunity to comment on the new, voluntary program for certain medical devices and device-led combination products that are reasonably expected to significantly improve the safety of currently available treatments or diagnostics that target an underlying disease or condition associated with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program. We support efforts to establish a program to expedite the availability of medical devices that demonstrate significant safety improvements. However, we recommend that the guidance provide a clear and detailed definition of "significantly" when describing the requirement for inclusion in the program of devices that have the potential to "significantly" improve safety. In addition to the definition, examples of devices that meet the standard for significantly improved safety and devices that do not meet the

standard should be included. The definition and examples will aid manufacturers in determining the appropriateness of their devices for the Safer Technologies Program.

AdvaMed commends and supports FDA for its efforts in establishing the Safer Technologies Program. Attachment A provides additional suggestions for the draft guidance.

Sincerely,

/s/

Ruey C. Dempsey
Vice President
Technology & Regulatory Affairs

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Safer Technologies Program for Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

Additions indicated in underline.
Deletions indicated in ~~strikethrough.~~

Line(s) No.	Change	Reason
General	Provide examples to help illustrate what FDA would consider to constitute a "significant" or "substantial" improvement to safety that would warrant inclusion in the program.	Throughout the document, FDA repeatedly uses the terms "significant" and "substantial," e.g., when describing the intent of the program and the program eligibility criteria. We would appreciate examples of both improvements that the Agency would deem to be significant and ones where the Agency would not consider the improvement to be significant. A similar approach was used in the modifications guidance, "Deciding When to Submit a 510(k) for a Change to an Existing Device," and was very helpful to industry.
141-142	FDA is responsible for protecting and promoting public health by ensuring the safety and effectiveness ~~and security~~ of medical products.	While use of the STeP program for changes related to device security may be appropriate, the review standard is safety and effectiveness.
142-144	Additionally, FDA has a role to play in ~~is responsible for~~ advancing public health by helping to provide timely access to innovations that make medical products and their use safer and more effective.	While we believe FDA has an important role to play in promoting timely access to innovations, the review standard is safety and effectiveness.

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241-244	Given that the purpose of STeP is earlier access to devices that address important safety issues, sponsors of devices under this program are expected to work interactively with FDA and respond to FDA requests, collect premarket and postmarket data, and market their devices, if authorized, in a timely manner. <u>The timeliness of the response is relative to the specific FDA request. For example, conducting a new study requires more time than responding to a request where the information is readily available.</u>	Provide additional context to promote uniform expectations and alignment as to what constitutes a "timely" response.
275-277	For devices in STeP, FDA intends to consider proposals for efficient and flexible clinical study designs, including those incorporating real world ~~data sources~~ <u>evidence</u>, that may be used to support the proposed indication and/or labeling.	FDA's recognition that Real World Evidence can be part of efficient and flexible clinical study designs used to support the proposed indication and/or labeling of the clinical benefit of a medical device is appreciated. For clarification purposes, we prefer the terms "real world evidence"; it is a more common term.
297-298	To be eligible for STeP, the device should be subject to marketing authorization via the PMA, *De Novo* request, or 510(k), <u>or Dual Submission (Dual 510(k) and CLIA Waiver by Application)</u> pathways.	Devices intended for Dual Submission pathway (where 510(k) review and CLIA Waiver review are performed using the same submission) should also be eligible for STeP. The eligibility factors of the STeP pathway (especially 2c) make it attractive for point-of-care (POC) diagnostic devices as use-related hazards and user errors are extensively studied and understood for POC diagnostic devices. Many POC devices are intended for use in a CLIA-Waived environment. If CLIA-waivable POC devices were forced to go through the sequential, separate 510(k) clearance followed by a separate

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		lengthy CLIA Waiver by Application process, it would introduce a greater delay in the availability of a potentially safer product. To enable safer POC CLIA waivable devices to reach patients sooner, please clarify that the devices intended for the Dual Submission pathway can be eligible for STeP.
312-313	"…due to the less serious nature of the disease or condition treated, e.g., example …"	Add examples to help illustrate the concept of "less serious."
335	"…would be considered non-life threatening, e.g., example, and reasonably reversible, e.g., example."	Add examples to help illustrate the concepts of "non-life threatening" and "reasonably reversible."
370	"…surface physicochemical properties, such as drug or polymer coating…"	Providing examples specific to the changes envisioned would provide helpful clarity. We provide a proposed example of a surface physiochemical property and would also appreciate addition of examples of software and material manufacturing methods.
423-427	d. An improvement in the safety of another device or intervention When evaluating this sub-part, FDA intends to consider if the medical device is reasonably expected to offer a specific type of improved safety benefit for another medical device or intervention. In some cases, this improved safety benefit might come from the device being evaluated for inclusion in STeP acting as an accessory.	Clarify that certain Software as a Medical Device (SaMD) apps and related digital health tools could qualify for inclusion into STeP. There are a variety of ways in which digital health tools could help improve the safety of other devices and interventions, e.g., by enabling greater compliance to a drug treatment regimen or by making clinicians more aware of existing

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	This subpart may, however, also apply to finished devices that are not accessories. For example, some software as a medical device (SaMD) apps or related digital health tools may qualify for inclusion into STeP.	treatment options. Some of these tools will qualify as medical devices requiring submission based on their intended use. While there are other voluntary programs such as the Software Precertification Program (currently in pilot phase) designed to expedite the market availability of certain SaMDs, not all SaMD products will be eligible for precertification. Therefore, additional options, such as STeP, are still helpful. To make such valuable tools available to patients sooner, please clarify that certain SaMD devices can be eligible for STeP.
487-489	Requests for inclusion in STeP should be submitted using the Q-submission process as described in the FDA guidance document "Requests for Feedback on Medical Device Submissions: The Q-Submission Program" (hereinafter, "the Q-Submission Guidance"). Requests may be submitted as supplements to an original Q-Submission as long as it's for the same device and the same indications/intended use.	It is not clear between the two guidance documents that this is an acceptable method for seeking FDA requests. This method has proven to be acceptable based on feedback from members of the industry who have previously interacted with FDA through the Breakthrough Devices Program.
503-507	In general, FDA intends to interact with a sponsor by Day 30 regarding any requests for additional information needed to evaluate the request. It is helpful when a sponsor is available and responsive to FDA requests throughout FDA's review. A request for additional information does not put the Safer request on hold and the	It is not clear how the review clock is impacted when an additional information request is received. To ensure efficient and effective communication, FDA should remain available and responsive to the sponsor if there are questions regarding the request for additional information. Further, if FDA has any outstanding questions following a sponsor's response to an

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	sponsor should respond with an amendment to the Q-submission within the timeframe stipulated in the additional information request. The sponsor may wish to contact the reviewer with any questions regarding the additional information request. If FDA does not receive additional information needed to evaluate a STeP request in a timely manner, it may result in denial of the request for inclusion in STeP. The FDA will continue to interact with the sponsor using tools such as email or telephone following submission of a response to an additional information request if additional questions arise.	additional information request, attempts should be made to communicate with the sponsor.
627-628	~~FDA does not plan to provide feedback on device development progress or data during status updates~~ FDA may provide informal high-level feedback on device development progress and express potential concerns based on the information provided and known at that point in time. Status update feedback from the agency is non-binding and is intended only to facilitate transparency between the review team and device manufacturers. Pre-submissions or sprint discussions should be utilized for formal feedback on topics, such as preliminary data results and unexpected clinical study complications.	Recommend this revision as the sentence makes it appear as though FDA will not provide feedback during regular status update interactions, which significantly diminishes the value of planning and scheduling update calls. The proposed revision would empower reviewers to have transparent, candid conversations with STeP participants to allow for improved study design and lead to more efficient marketing submission review. It would also provide a mechanism for device manufacturers to present unforeseen problems or complications that the FDA can be more prepared to discuss in a subsequent sprint discussion or pre-submission by allowing the FDA reviewer to tell the device manufacturer what information is needed to foster such a meeting and discussion. We believe our proposed revision would improve regular status update interactions and help eliminate unforeseen issues from arising when the marketing application is submitted for FDA review.